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EXAMINER

YANG, NELSON C

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1641

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/698,289	Applicant(s) WOLF, DAVID E.	
	Examiner NELSON YANG	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-92 is/are pending in the application.
- 4a) Of the above claim(s) 48-55 and 66-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-47, 56-65 and 84-92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Election/Restrictions

2. The election of species requirement on January 24, 2007, has been withdrawn. As a result, claims 43, 87, and 88 are rejoined.
3. The restriction requirement with respect to claim 1 has been withdrawn, as claim 1 now encompasses subject matter included in the claims being examined. Claim 1 has therefore been rejoined.
4. Claims 1-47, 56-65, 84-92 are currently under examination.
5. Claims 48-55, 66-83 are withdrawn.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 56, 58-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Kain et al. [US 5,754,291].

With respect to claim 56, Kain et al. teach a laser light source (column 4, lines 60-65) and an array detector sensing elements such as photo diodes or CCD array (column 4, lines 13-18),

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capable of measuring fluorescence from a sample system (sensor) (column 5, lines 13-20, column 8, lines 20-27). and further teach a double objective lens assembly which provides a constant image definition so that a number of resolvable points across the field correspond to a number of pixel elements of a detector (column 2, lines 53-57), such that a full-field view of the sample may be obtained to obtain a full image of the sample without having to move the sample or scan a line (column 3, lines 10-17). The photodiode array and CCD array would therefore be chips that are optically coupled to the excitation source.

8. With respect to claim 58, Kain et al. teach a laser light source (column 4, lines 60-65) which would be capable of transcutaneous excitation.

9. With respect to claim 59, Kain et al. teach an array detector sensing elements such as photo diodes or CCD array (column 4, lines 13-18), which would be capable of detecting light emitted transcutaneously.

10. With respect to claim 60, Kain et al. teach a signal processor (column 3, lines 40-45).

11. With respect to claim 61, Kain et al. teach a laser light source (column 4, lines 60-65) and an array detector sensing elements such as photo diodes or CCD array (column 4, lines 13-18), capable of measuring fluorescence from a sample system (sensor) (column 5, lines 13-20, column 8, lines 20-27). and further teach a double objective lens assembly which provides a constant image definition so that a number of resolvable points across the field correspond to a number of pixel elements of a detector (column 2, lines 53-57), such that a full-field view of the sample may be obtained to obtain a full image of the sample without having to move the sample or scan a line (column 3, lines 10-17).

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12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1, 30, 2, 3, 5-8, 13, 14, 16-19, 22, 24, 25, , 31, 32, 34-37, 41-47, 84-88, 92, are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballerstadt et al. [US 6,454,710] in view of Stern [US 5,981,956].

With respect to claims 1, 30, Ballerstadt et al. teach a device comprising a hydrogel (column 4, lines 42-48) and surrounded by an analyte permeable membrane (column 5, lines 65-67) for detecting multiple analytes simultaneously using labeled analogues matched to each of the analytes of interest (column 3, lines 3-15). Ballerstadt et al. further teach a reference dye (column 6, lines 46-50), excitation sources (column 10, lines 63-65) and detection systems including photodiodes, avalanche diodes, CCDs, and photomultipliers (column 11, lines 4-7), such that the fluorescence emission may be measured at specific wavelengths (column 11, lines 5-25). Ballerstadt et al. do not specifically teach three detectors adapted to measure different wavelengths.

Stern, however, teaches an array comprising regions (features - column 7, lines 10-15) containing different polymer sequences to be coupled in different known locations on the substrate surface (object) (column 5, lines 48-60). Target sequences labeled with detectable groups (probes) are contacted with the array (column 6, lines 52-60), where multiple probes may be used (column 8, lines 25-30). Dichroic mirrors or beam splitters are used to separate signals from label groups having different response radiation wavelengths, thereby allowing

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simultaneous detection of multiple fluorescent indicators (column 10, lines 15-35), where the response radiation from the targets are individually detected through additional detectors such as photomultiplier tubes (column 10, lines 33-50).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used the multiple detection systems of Stern in lieu of the detector of Ballerstadt et al., in order to allow for the simultaneous interrogation of multiple different labeled analogues and the reference dye, while minimizing the potential interference of the signals with each other.

14. With respect to claims 2, 31, Ballerstadt et al. teach excitation sources (column 10, lines 63-65) for excitation when the device is implanted (column 10, lines 65-67).

15. With respect to claims 3, 32, Ballerstadt et al. teach detection systems for detecting the labels when the device is implanted (column 11, lines 25-35).

16. With respect to claims 5, 6, 34, Ballerstadt et al. teach light filtering devices (column 11, lines 13-18).

17. With respect to claims 7-8, 35-37, Ballerstadt et al. teach first, second, and third dichroic mirrors (column 10, lines 15-35), which are positioned to reflect light from both the excitation source and the sensor (fig.1).

18. With respect to claim 13, Ballerstadt et al. teach that the labeled analogues are mobile within the matrix (column 3, lines 35-45).

19. With respect to claim 14, Stern teaches computers for recording data (column 3, lines 59-61).

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20. With respect to claims 16-17, Stern teaches that the response radiation from the targets are individually detected through additional detectors such as photomultiplier tubes (column 10, lines 33-50) and computers are used for recording data (column 3, lines 59-61). Therefore the computer would be capable of relating signals with the concentration of the analyte.

21. With respect to claim 18, 19, Stern teaches computers for controlling and recording data (column 3, lines 59-61), and would therefore be capable of providing instructions and alarms relating to the amount of detected analyte, such as displaying the concentration of detected analyte.

22. With respect to claims 22, Ballserstadt et al. teach detection of chemotherapeutic drugs and glucose (column 3, lines 4-16).

23. With respect to claim 24, Ballerstadt et al. teach a CCD detector (column 11, lines 4-6), which a semiconductor based detector.

24. With respect to claim 25, Stern teaches simultaneous detection of multiple fluorescent indicators (column 10, lines 15-35), where the response radiation from the targets are individually detected through additional detectors such as photomultiplier tubes (column 10, lines 33-55).

25. With respect to claim 41, the detectors taught by Stern would be capable of detecting light, such as that emitted by skin.

26. With respect to claims 42-47, Ballerstadt et al. teach a device comprising a hydrogel (column 4, lines 42-48) and surrounded by an analyte permeable membrane (column 5, lines 65-67) for detecting multiple analytes simultaneously using labeled analogues matched to each of the analytes of interest (column 3, lines 3-15). Ballerstadt et al. further teach a reference dye

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(column 6, lines 46-50) such that the ratio of signal from the reference to the signal from the analyte is dependent on concentration of analyte (column 7, lines 15-25), excitation sources (column 10, lines 63-65) and detection systems including photodiodes, avalanche diodes, CCDs, and photomultipliers (column 11, lines 4-7), such that the fluorescence emission may be measured at specific wavelengths (column 11, lines 5-25). Stern teaches that the response radiation from the targets are individually detected through additional detectors such as photomultiplier tubes (column 10, lines 33-50) and computers are used for recording data (column 3, lines 59-61). Therefore, one of ordinary skill in the art would have found it obvious to program the computer to process signals with the concentration of the analyte and the reference signal to determine the concentration of the different analytes in the manner as specified by Ballerstadt et al.

27. With respect to claim 84, Ballerstadt et al. teach excitation sources such as LEDs (column 10, lines 63-67)

28. With respect to claims 85 and 86, Ballerstadt et al. teach light filtering devices (column 11, lines 13-18).

29. With respect to claims 87 and 88, Ballerstadt et al. teach first, second, and third dichroic mirrors (column 10, lines 15-35), which are positioned to partially reflect light from both the excitation source and the sensor (fig.1).

30. With respect to claim 92, Ballerstadt et al. teach a device comprising a hydrogel (column 4, lines 42-48) and surrounded by an analyte permeable membrane (column 5, lines 65-67) for detecting multiple analytes simultaneously using labeled analogues matched to each of the analytes of interest (column 3, lines 3-15). Ballerstadt et al. teach that the labeled analogues are

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mobile within the matrix (column 3, lines 35-45). Ballerstadt et al. further teach a reference dye (column 6, lines 46-50), excitation sources (column 10, lines 63-65) and detection systems including photodiodes, avalanche diodes, CCDs, and photomultipliers (column 11, lines 4-7), such that the fluorescence emission may be measured at specific wavelengths (column 11, lines 5-25). Ballerstadt et al. do not specifically teach three detectors adapted to measure different wavelengths.

Stern, however, teaches an array comprising regions (features - column 7, lines 10-15) containing different polymer sequences to be coupled in different known locations on the substrate surface (object) (column 5, lines 48-60). Target sequences labeled with detectable groups (probes) are contacted with the array (column 6, lines 52-60), where multiple probes may be used (column 8, lines 25-30). Dichroic mirrors or beam splitters are used to separate signals from label groups having different response radiation wavelengths, thereby allowing simultaneous detection of multiple fluorescent indicators (column 10, lines 15-35), where the response radiation from the targets are individually detected through additional detectors such as photomultiplier tubes (column 10, lines 33-50).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used the multiple detection systems of Stern in lieu of the detector of Ballerstadt et al., in order to allow for the simultaneous interrogation of multiple different labeled analogues and the reference dye, while minimizing the potential interference of the signals with each other.

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31. Claims 4, 15, 28, 29, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballerstadt et al. [US 6,454,710] in view of Stern [US 5,981,956], as applied to claim 30 above, and further in view of Zenhausern [US 2002/0094531].

With respect to claims 4, 15, and 33 Ballerstadt et al. teach the invention as discussed above, but fail to teach a telemetry system for transmitting the light signals to a remote location.

Zenhausern, however, teaches a transmission means capable of transmitting a signal between a multivariate detector and a data acquisition system (para. 0051), wherein the communications method may be wireless (para. 0059).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used a wireless telemetry system, as suggested by Zenhausern, in order to transmit the signals of Ballerstadt et al. to a remote location, in order to avoid the inconvenience of wires and the flexibility of being able to move the detectors around more.

32. With respect to claims 28, 29, Zenhusern teaches a pump (para. 0080), which would be capable of drawing interstitial fluid or blood. Zenhausern et al. further teach that the pump allows for the transport of a sample to be detected and to an exhaust or waste reservoir.

33. Claims 9-11 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballerstadt et al. [US 6,454,710] in view of Stern [US 5,981,956], as applied to claim 30 above, and further in view of Schultz [US 6,256,522].

With respect to claims 9-11, 38-40, Ballerstadt et al. teach the invention as discussed above, but fail to teach optical fibers connected to the excitation source.

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Schultz discloses optical fibers connected to a light source and detection means (column 4, lines 40-45) in a sensor system comprising a gel comprising molecules of receptor material covalently bonded to strands of polymers (column 6, lines 1-11), encapsulated in a semi-permeable membrane (column 5, lines 45-65). Schultz also teaches a light source for shining excitation light (column 7, lines 10-15) and detection means for measuring fluorescence (column 8, lines 28-38). Schultz further teaches that more than two different receptor materials and associated dyes can be used to detect more than two analytes (column 13, lines 10-21).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used the light source system of Schultz comprising optical fibers, due to the added flexibility of being able to maneuver where the light was delivered to the sensor, without moving the actual location of the light source itself.

34. Claims 12, 20, 21, 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballerstadt et al. [US 6,454,710] in view of Stern [US 5,981,956], as applied to claims 19 and 30 above, and further in view of Martin et al. [US 2002/0016535].

With respect to claims 12, 20, Ballerstadt et al. teach the invention as discussed above, but fail to teach that the instructions are to administer insulin, glucose, or a combination thereof, but fail to teach that the sensor detects glucose, provides an alarm, or administers insulin.

Martin et al., however, teach a glucose sensor incorporated with an insulin pump (para. 0061) in order to provide a glucose measuring and insulin delivery system that allow the return of near normal functioning of the body (para. 0061).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used the device of Schultz et al. to measure glucose as suggested by Martin et al., in order to allow the return of normal function to the bodies of patients with diabetes.

35. With respect to claim 21, Martin further teach an alarm when a glucose levels are becoming to high or low or when there is no response (para. 0058), which ensures that the sensor is working properly (para. 0053).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated an alarm in the device of Empedocles et al., as suggested by Martin et al., in order ensure that the sensor is working properly.

36. With respect to claim 91, Ballerstadt et al. teach a device comprising a hydrogel (column 4, lines 42-48) and surrounded by an analyte permeable membrane (column 5, lines 65-67) for detecting multiple analytes simultaneously using labeled analogues matched to each of the analytes of interest (column 3, lines 3-15). Ballerstadt et al. further teach a reference dye (column 6, lines 46-50), excitation sources (column 10, lines 63-65) and detection systems including photodiodes, avalanche diodes, CCDs, and photomultipliers (column 11, lines 4-7), such that the fluorescence emission may be measured at specific wavelengths (column 11, lines 5-25). Ballerstadt et al. do not specifically teach three detectors adapted to measure different wavelengths, or a pump for delivering medicament in response to an instruction.

Stern, however, teaches an array comprising regions (features - column 7, lines 10-15) containing different polymer sequences to be coupled in different known locations on the substrate surface (object) (column 5, lines 48-60). Target sequences labeled with detectable

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groups (probes) are contacted with the array (column 6, lines 52-60), where multiple probes may be used (column 8, lines 25-30). Dichroic mirrors or beam splitters are used to separate signals from label groups having different response radiation wavelengths, thereby allowing simultaneous detection of multiple fluorescent indicators (column 10, lines 15-35), where the response radiation from the targets are individually detected through additional detectors such as photomultiplier tubes (column 10, lines 33-50).

Martin et al. further teach a glucose sensor incorporated with an insulin pump (para. 0061) in order to provide a glucose measuring and insulin delivery system that allow the return of near normal functioning of the body (para. 0061).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used the multiple detection systems of Stern in lieu of the detector of Ballerstadt et al., in order to allow for the simultaneous interrogation of multiple different labeled analogues and the reference dye, while minimizing the potential interference of the signals with each other. It would further have been obvious to one of ordinary skill in the art at the time of the invention to have used the device of Schultz et al. to measure glucose as suggested by Martin et al., in order to allow the return of normal function to the bodies of patients with diabetes.

37. Claims 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballerstadt et al. [US 6,454,710] in view of Stern [US 5,981,956], as applied to claim 30 above, and further in view of Empedocles et al. [US 2002/0031783].

With respect to claims 26, Ballerstadt et al. and Stern disclose the claimed invention except that they teach a laser instead of a pulsed laser. Empedocles shows that lasers and pulsed

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lasers (para. 0098) are an equivalent structure known in the art. Therefore, because these two types of lasers were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute a pulsed laser for a laser.

With respect to claim 27, Stern teaches a computer (column 3, lines 59-61) which would be capable of phase locking the counting of signals at the detector with the pulse emitted by the lasers.

38. Claims 57, 62-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kain et al. [US 5,754,291], as applied to claim 56, and further in view of Zenhausern [US 2002/0094531].

With respect to claim 57, Kain et al. teach an array detector sensing elements such as photo diodes or CCD array (column 4, lines 13-18), capable of measuring fluorescence from a sample system (sensor) (column 5, lines 13-20, column 8, lines 20-27). and further teach a double objective lens assembly which provides a constant image definition so that a number of resolvable points across the field correspond to a number of pixel elements of a detector (column 2, lines 53-57), such that a full-field view of the sample may be obtained to obtain a full image of the sample without having to move the sample or scan a line (column 3, lines 10-17). The photodiode array and CCD array would therefore be chips that are optically coupled to the excitation source. Kain et al. fail to teach a transmitter.

Zenhausern, however, teaches a transmission means capable of transmitting a signal between a multivariate detector and a data acquisition system (para. 0051), wherein the communications method may be wireless (para. 0059).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used a wireless system, as suggested by Zenhausern, in order to transmit the signals of Ballerstadt et al. to a remote location, in order to avoid the inconvenience of wires and the flexibility of being able to move the detectors around more.

With respect to claim 62, Zenhausern teaches a multiplexer which would convert the signal from analog to digital before outputting the data to the computer (para. 0090).

39. With respect to claim 63, the computer taught by Zenhausern would comprise a clock (para. 0090).

40. With respect to claim 64, Zenhausern teaches a transmission means capable of transmitting a signal between the multivariate detector and a data acquisition system (para. 0051), wherein the communications method may be wireless (para. 0059).

41. With respect to claim 65, Zenhausern teaches comparing the analysis of the signals at several wavelengths with the properties of the analyte as a result of surface interactions (para. 0034), such as changes in concentration (claim 13).

42. Claims 89-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballerstadt et al. [US 6,454,710] in view of Stern [US 5,981,956], as applied to claim 30 above, and further in view of Kain et al. [US 5,754,291].

With respect to claims 89, 90, Ballerstadt et al. and Stern teach the invention as discussed above. Ballerstadt et al. further teach photodiodes, CCDs (column 11, lines 4-6), but fail to specifically state that these detectors are arrays.

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Kain et al., however, teach an array detector sensing elements such as photo diodes or CCD array (column 4, lines 13-18), and further teach a double objective lens assembly which provides a constant image definition so that a number of resolvable points across the field correspond to a number of pixel elements of a detector (column 2, lines 53-57), such that a full-field view of the sample may be obtained to obtain a full image of the sample without having to move the sample or scan a line (column 3, lines 10-17). The photodiode array and CCD array would therefore be chips that are optically coupled to the excitation source.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used the detector of Kain et al., wherein that a number of resolvable points across the field correspond to a number of pixel elements of a detector such that different components of a cell that fluoresce at different wavelengths would be collected on different locations in the invention of Ballerstadt et al. and Stern, as suggested by Kain et al. such that a full-field view of the sample may be obtained to obtain a full image of the sample without having to move the sample or scan a line, thus reducing the potential for error and noise.

Response to Arguments

43. Applicant's arguments with respect to claims 2 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

44. No claims are allowed.

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45. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571)272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

46. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nelson Yang/
Patent Examiner, Art Unit 1641